

(ii) *Indications for use.* For use in cats 6 weeks of age and older, for control of flea populations. Lufenuron controls flea populations by preventing the development of flea eggs and does not kill adult fleas. Concurrent use of insecticides may be necessary for adequate control of adult fleas.

(iii) *Limitations.* For subcutaneous use in cats only. The safety of this product in reproducing animals has not been established. Do not use in dogs. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[63 FR 29552, June 1, 1998]

#### § 522.1290 Luprostiol sterile solution.

(a) *Specifications.* Each milliliter of sterile solution contains 7.5 milligrams of luprostiol.

(b) *Sponsor.* See No. 057926 in § 510.600(c) of this chapter.

(c) *Special considerations.* Labeling shall bear the following statements: *Warning:* Women of childbearing age, asthmatics, and persons with bronchial and other respiratory problems should exercise extreme caution when handling this product. In the early stages, women may be unaware of their pregnancies. Luprostiol is readily absorbed through the skin and can cause abortion and/or bronchospasms. Direct contact with the skin should therefore be avoided. Accidental spillage on the skin should be washed off immediately with soap and water.

(d) *Conditions of use—(1) Amount.* 7.5 milligrams per mare.

(2) *Indications for use.* The drug is used in mares for estrus control and termination of pregnancy.

(3) *Limitations.* Administer by intramuscular injection only. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[55 FR 1185, Jan. 12, 1990, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995; 61 FR 66582, Dec. 18, 1996]

#### § 522.1335 Medetomidine hydrochloride injection.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 1.0

milligram of medetomidine hydrochloride.

(b) *Sponsor.* See 052483 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount.* 750 micrograms intravenously (IV) or 1,000 micrograms intramuscularly per square meter of body surface. The IV route is more efficacious for dental care.

(2) *Indications for use.* As a sedative and analgesic in dogs over 12 weeks of age to facilitate clinical examinations, clinical procedures, minor surgical procedures not requiring muscle relaxation, and minor dental procedures not requiring intubation. The intravenous route of administration is more efficacious for dental care.

(3) *Limitations.* Do not use in dogs with cardiac disease, respiratory disorders, liver or kidney diseases, dogs in shock, dogs which are severely debilitated, or dogs which are stressed due to extreme heat, cold, or fatigue. Allow agitated dogs to rest quietly before administration. Do not repeat dosing in dogs not responding satisfactorily to treatment. Do not use in breeding or pregnant animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[61 FR 21075, May 9, 1996]

#### § 522.1350 Melatonin implant.

(a) *Specifications.* The drug is a silicone rubber elastomer implant containing 2.7 milligrams of melatonin.

(b) *Sponsor.* See No. 053923 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount.* One implant per mink.

(2) *Indications for use.* For use in healthy male and female kit and adult female mink (*Mustela vison*) to accelerate the fur priming cycle.

(3) *Limitations.* For subcutaneous implantation in mink only. Do not implant potential breeding stock. Do not use in food-producing animals.

[59 FR 37422, July 22, 1994]

#### § 522.1362 Melarsomine dihydrochloride for injection.

(a) *Specifications.* The drug consists of a vial of lyophilized powder containing 50 milligrams of melarsomine dihydrochloride which is reconstituted

with the provided 2 milliliters of sterile water for injection.

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* For asymptomatic to moderate (class 1 to class 2) heartworm disease: 2.5 milligrams per kilogram of body weight (1.1 milligram per pound) twice, 24 hours apart. The series can be repeated in 4 months depending on the response to the first treatment and the condition, age, and use of the dog. For severe (class 3) heartworm disease: Single injection of 2.5 milligrams per kilogram followed, approximately 1 month later, by 2.5 milligrams per kilogram administered twice, 24 hours apart.

(2) *Indications.* Treatment of stabilized, class 1, 2, and 3 heartworm disease (asymptomatic to mild, moderate, and severe, respectively) caused by immature (4 month-old, stage L<sub>5</sub>) to mature adult infections of *Dirofilaria immitis* in dogs.

(3) *Limitations.* Administer only by deep intramuscular injection in the lumbar muscles (L<sub>3</sub>-L<sub>5</sub>). Use a 23 gauge 1 inch needle for dogs less than or equal to 10 kilograms (22 pounds) and a 22 gauge 1 1/2 inch needle for dogs greater than 10 kilograms (22 pounds). Use alternate sides with each administration. The drug is contraindicated in dogs with class 4 (very severe) heartworm disease (Caval Syndrome). Not for use in breeding animals and lactating or pregnant bitches. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[60 FR 49340, Sept. 25, 1995]

**§ 522.1367 Meloxicam.**

(a) *Specifications.* Each milliliter of solution contains 5.0 milligrams (mg) meloxicam.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer 0.09 mg per pound (mg/lb) body weight (0.2 mg per kilogram (mg/kg)) by intravenous or subcutaneous injection on the first day of treatment. For treatment after day 1, administer meloxicam suspension orally at 0.045 mg/lb (0.1 mg/kg) body weight once daily as in § 520.1350(c) of this chapter.

(ii) *Indications for use.* For the control of pain and inflammation associated with osteoarthritis.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount.* Administer 0.14 mg/lb (0.3 mg/kg) body weight as a single, one-time subcutaneous injection.

(ii) *Indications for use.* For the control of postoperative pain and inflammation associated with orthopedic surgery, ovariohysterectomy, and castration when administered prior to surgery.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[68 FR 68724, Dec. 10, 2003, as amended at 69 FR 69523, Nov. 30, 2004]

**§ 522.1372 Mepivacaine hydrochloride injection.**

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 20 milligrams of mepivacaine hydrochloride.

(b) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer 0.09 mg per pound (mg/lb) body weight (0.2 mg per kilogram (mg/kg)) by intravenous or subcutaneous injection on the first day of treatment. For treatment after day 1, administer meloxicam suspension orally at 0.045 mg/lb (0.1 mg/kg) body weight once daily as in § 520.1350(c) of this chapter.

(ii) *Indications for use.* For the control of pain and inflammation associated with osteoarthritis.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount.* Administer 0.14 mg/lb (0.3 mg/kg) body weight as a single, one-time subcutaneous injection.

(ii) *Indications for use.* For the control of postoperative pain and inflammation associated with orthopedic surgery, ovariohysterectomy, and castration when administered prior to surgery.